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भारतीय मानक

गुणता प्रबंध पद्धतियाँ — पॉवर सेक्टर उपकरण निर्माण, सेवा तथा यूटिलिटी संगठन के लिए आईएसओ 9001 : 2008 के अनुप्रयोग की विशेष अपेक्षाएँ

Indian Standard

QUALITY MANAGEMENT SYSTEMS — PARTICULAR REQUIREMENTS FOR THE APPLICATION OF ISO 9001 : 2008 FOR POWER SECTOR EQUIPMENT MANUFACTURING, SERVICE AND UTILITY ORGANIZATION

ICS 03.120.10;27.100

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NEW DELHI 110002

February 2013 **Price Group 10**

Quality Management Sectional Committee, MSD 2

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Quality Management Sectional Committee had been approved by the Management and Systems Division Council.

The power demand in India is very high and to keep up the pace with development of Indian economy high availability and plant load factors are essential. The power plant equipment and system is very complex and requires effective quality assurance system and procedure in order to achieve high availability and reliability. This standard is formulated to meet this objective and the specific requirements for power sector specially taking care of Indian conditions. The experience of leading power utilities operating in India has been carefully considered while formulating these requirements. The requirements should help the Indian power sector a great deal in their quality initiative.

Wherein the text in the boxes gives the text of IS/ISO 9001 : 2008 'Quality management systems — Requirements (*third revision*)' and the text outside the boxes gives the requirement.

In formulating this standard considerable assistance has been taken from IS/ISO/TS 16949 : 2009 'Quality management systems — Particular requirements for the application of ISO 9001 : 2008 for automotive production and relevant service part organizations (*second revision*)', IS/ISO 9001 : 2008 'Quality management systems — Requirements (*third revision*)' and IS/ISO 9004 : 2009 'Managing for the sustained success of an organization — A quality management approach (*sixth revision*)'.

The composition of the Committee responsible for the formulation of this standard is given in Annex C.

Indian Standard

QUALITY MANAGEMENT SYSTEMS — PARTICULAR REQUIREMENTS FOR THE APPLICATION OF ISO 9001 : 2008 FOR POWER SECTOR EQUIPMENT MANUFACTURING, SERVICE AND UTILITY ORGANIZATION

1 Scope

1.1 General

> **ISO 9001 : 2008, Quality Management Systems — Requirements**
>
> **1 Scope**
>
> **1.1 General**
>
> This International Standard specifies requirements for a quality management system where an organization
>
> a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
> b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
>
> NOTE 1 In this International Standard, the term "product" only applies to
>
> a) product intended for, or required by, a customer,
> b) any intended output resulting from the product realization processes.
>
> NOTE 2 Statutory and regulatory requirements can be expressed as legal

1.1.1 This standard, in combination with IS/ISO 9001 : 2008 'Quality management systems — Requirements (*third revision*)' defines the quality management system requirements for the design and development, manufacture, installation, operation and services of power sector products.

1.2 Application

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **1.2 Application**
>
> All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

1.2.1 This standard is applicable to the organization where equipment for generation, transmission, and distribution of power are designed, manufactured, installed, operated and maintained.

1.2.2 Exclusions are not permitted for this standard as for power projects a systems design is essential for any project in view of site specific requirements and hence design needs to be controlled and permitted exclusions do not include manufacturing process design.

2 References

The standards listed below contain provisions, which through reference in this text constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
12040 : 2001	Guidelines for development of supplier rating system (*first revision*)
IS/ISO 9000 : 2005	Quality management systems — Fundamentals and vocabulary (*third revision*)
IS/ISO 9001 : 2008	Quality management systems — Requirements (*third revision*)
IS/ISO 9004 : 2009	Managing for the sustained success of an organization — a quality management approach (*sixth revision*)
IS/ISO/IEC 17025 : 2005	General requirements for the competence of testing and calibration laboratories

3 Terms and Definitions

3.1 Terms and Definitions for the Power Industry

For the purpose of this standard, the terms and definitions given to ISO 9000 and the following shall apply.

3.1.1 *Quality Control Plan (QCP)* — A document setting out the specific quality practices and procedures relevant to a particular component, part or a material (*see* Annex A).

3.1.2 *CIP* — CIP 'Customer Interaction Point' is a stage identified by customer in quality plan, which is to be offered to customer or authorized representative for witnessing, verification or review, beyond which the work shall not proceed without the written consent of the customer.

3.1.3 *Non-conformance* — Non-conformances have two categories major and minor. Major non-conformances are those which have a direct or indirect adverse effect on performance, reliability, safety, interchangeability, maintainability or on working life of the material, equipment or service. All other non-conformances are classified as minor.

3.1.4 *Categorization of QCP/Quality Control Plan*

a) *Category* I — Quality control plan approval by customer and physical inspection by customer is envisaged.
b) *Category* II — Quality control plan approval by customer but no physical inspection by customer is envisaged.
c) *Category* III — No quality control plan approval by customer is envisaged. The controls shall be applicable as per supplier's own quality assurance system.

3.1.5 *Field Welding Schedule* — The form used to document field weld locations, numbers, welding procedure to be used, technical requirements, code requirements and non-destructive examination requirements for a specific contract.

4 Quality Management System

4.1 General Requirements

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **4 Quality management system**
>
> **4.1 General requirements**
>
> The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall
>
> a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
> b) determine the sequence and interaction of these processes,
> c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
> d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
> e) monitor, measure where applicable, and analyse these processes, and
> f) implement actions necessary to achieve planned results and continual improvement of these processes.
>
> These processes shall be managed by the organization in accordance with the requirements of this International Standard.
>
> Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.
>
> NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.
>
> NOTE 2 An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.
>
> NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as
>
> a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements,
> b) the degree to which the control for the process is shared,
> c) the capability of achieving the necessary control through the application of 7.4.

4.1.1 *General Requirements — Supplemental*

Ensuring control over outsourced processes shall not absolve the organization of the responsibility of conformity to all customer requirements.

Outsourcing shall be subject to any contractual agreement. If outsourcing is required after order has been received then the customer shall be suitably involved

NOTE — See also **7.4.1** and **7.4.1.3**.

4.2 Documentation Requirements

4.2.1 *General*

ISO 9001 : 2008, Quality Management systems — Requirements

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures and records required by this International Standard, and

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.1.1 Organization shall ensure latest versions of documents are accessable to all concerned in all work places and preferably in soft form.

4.2.2 *Quality Manual*

ISO 9001 : 2008, Quality Management systems — Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 *Control of Documents*

ISO 9001 : 2008, Quality Management systems — Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.3.1 *Quality control plans (shop activities/field services) and engineering drawings/datasheets*

The organization shall have a process to assure the timely review, approval, and distribution for implementation of all customer approved engineering drawings, datasheets, Quality control plans and including customer effected changes.

The organization shall maintain a record of the date on which each change is implemented in production.

4.2.4 *Control of Records*

ISO 9001 : 2008, Quality Management systems — Requirements

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.

4.2.4.1 *Records retention*

The control of records shall satisfy statutory and regulatory and customer requirements.

4.2.4.2 The records as agreed to be submitted to the customer as history of the equipment shall be compiled and submitted to the customer within agreed time of dispatch of respective products.

5 Management Responsibility

5.1 Management Commitment

ISO 9001 : 2008, Quality Management systems — Requirements

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established,
d) conducting management reviews, and
e) ensuring the availability of resources.

5.1.1 *Process Efficiency*

Top management shall periodically review the product realization processes and the support processes including timely deliveries to assure their effectiveness and efficiency .

5.2 Customer Focus

ISO 9001 : 2008, Quality Management systems — Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality Policy

ISO 9001 : 2008, Quality Management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 *Quality Objectives*

ISO 9001 : 2008, Quality Management systems — Requirements

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.1.1 *Quality objectives — Supplemental*

Top management shall define quality objectives and their measurements that shall be included in the operations plan and used to deploy the quality policy.

5.4.1.2 Quality objectives should ensure that all customer requirements are addressed and be achievable within a defined time period.

5.4.2 *Quality Management System Planning*

ISO 9001 : 2008, Quality Management systems — Requirements

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.4.2.1 A detailed quality management programme including quality control plan shall be prepared and mutually agreed with the customer before start of design, manufacture, installation and operation setting out the quality practices to be followed for the project .

5.5 Responsibility, Authority and Communication

5.5.1 *Responsibility and Authority*

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **5.5 Responsibility, authority and communication**
>
> **5.5.1 Responsibility and authority**
>
> Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.1.1 *Responsibility for quality*

Responsibility and authority for quality related decisions including rejection / stopping production shall be defined. Communication channels shall be established to ensure that quality problems are brought to the attention of the person/s assigned the responsibility.

5.5.2 *Management Representatives*

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **5.5.2 Management representative**
>
> Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes
>
> a) ensuring that processes needed for the quality management system are established, implemented and maintained,
>
> b) reporting to top management on the performance of the quality management system and any need for improvement, and
>
> c) ensuring the promotion of awareness of customer requirements throughout the organization.
>
> NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.2.1 *Customer coordinator*

Management shall designate personnel with responsibility and authority to ensure that customer requirements are fully addressed and coordinate with customers as a single point responsibility.

5.5.3 *Internal Communication*

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 *General*

> Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
>
> Records from management reviews shall be maintained (see 4.2.4).

5.6.1.1 *Quality management system performance*

These reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process.

Part of management review shall be the monitoring of quality objectives, and the regular reporting and evaluation of the benefits accrued to the organization and to be periodically reviewed (*see* **8.4.1** and **8.5.1**).

These results shall be recorded to provide, as a minimum, evidence of the achievement of,

- a) the quality objectives specified in the business plan;
- b) customer satisfaction with product supplied; and
- c) benefits accrued.

5.6.2 *Review Input*

The input to management review shall include information on

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) Changes that could affect the quality management system, and
- g) Recommendations for improvement.

5.6.2.1 *Review input — supplemental*

Input to management review shall include an analysis of actual and potential site failures and their impact on quality, safety or the environment.

5.6.3 *Review Output*

The output from the management review shall include any decisions and actions related to

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) Resource needs.

6 Resource Management

6.1 Provision of Resources

ISO 9001 : 2008, Quality Management systems — Requirements

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

- a) to implement and maintain the quality management system and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 *General*

ISO 9001 : 2008, Quality Management systems — Requirements

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 *Competence, Awareness and Training*

ISO 9001 : 2008, Quality Management systems — Requirements

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary competence,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.2.2.1 *Skills*

a) Organization shall identify skill required to perform and maintain skill matrix of all employees including outsourced personnel who may be employed for a particular project.

b) The organization shall ensure that personnel with product design responsibility are competent to achieve requirements and are skilled in applicable tools and techniques. In case of a collaboration design adequate checks shall be built to ensure proper transfer of technology. Know how and know why shall be traceable from technology provider.

6.2.2.2 *Training*

The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting conformity to product requirements. Personnel performing and supervising specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements. Special emphasis shall be laid for qualification of personnel performing special processes like welding, brazing, NDT, etc.

6.2.2.3 *Training on the job*

The organization shall provide on-the-job training for personnel in any new or modified job affecting product quality, including sub-contractor personnel. Personnel whose work can affect quality shall be informed about the consequence to the customer of non-conformity to quality requirements.

6.2.2.4 *Employee involvement*

The organization shall have a process to involve employees to achieve quality objectives, to make continual improvement, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

ISO 9001 : 2008, Quality Management systems — Requirements

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport, communication or information systems).

6.3.1 *Plant, Facility and Equipment Planning*

The organization shall use a multi-disciplinary approach for developing plant, facility and equipment plans. Methods shall be developed and implemented to evaluate and monitor the effectiveness of operation to produce consistently quality products design, manufacturing, installation and operation of a project as per agreed norms. The organization shall prepare contingency plan to satisfy customer requirements in the event of any emergency such as utility interruption or key equipment failure. In case of any abnormal happening, contingency plans to be prepared and mutually agreed upon with the equipment supplier /customer.

6.4 Work Environment

ISO 9001 : 2008, Quality Management systems — Requirements

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

6.4.1 *Cleanliness of Premises*

The organization shall maintain its premises in a state or order, cleanliness, and repair consistent with the product and manufacturing process needs. Wherever required, clean conditions shall be provided in manufacturing processes, sub-stations, control room, GIS assembly bay etc, for manufacture, assembly or operation of equipments.

7 Product Realization

7.1 Planning of Product Realization

ISO 9001 : 2008, Quality Management systems — Requirements

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;
b) the need to establish processes and documents, and to provide resources specific to the product;
c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization’s method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.1 *Planning of Product Realization — Supplemental*

Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan.

7.1.2 *Acceptance Criteria*

Acceptance criteria shall be defined in quantitative terms by the organization and, where required, mutually agreed with the customer.

7.2 Customer-Related Process

7.2.1 *Determination of Requirements Related to the Product*

> ## ISO 9001 : 2008, Quality Management systems — Requirements
>
> ### 7.2 Customer-related processes
>
> ### 7.2.1 Determination of requirements related to the product
>
> The organization shall determine
>
> a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
> b) requirements not stated by the customer but necessary for specified or intended use, where known,
> c) statutory and regulatory requirements applicable to the product, and
> d) any additional requirements considered necessary by the organization.
>
> NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 *Review of Requirements Related to the Product*

> ## ISO 9001 : 2008, Quality Management systems — Requirements
>
> ### 7.2.2 Review of requirements related to the product
>
> The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that
>
> a) product requirements are defined,
> b) contract or order requirements differing from those previously expressed are resolved, and
> c) the organization has the ability to meet the defined requirements.
>
> Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).
>
> Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.
>
> Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
>
> NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.2.1 *Organization manufacturing capability and capacity*

The organization shall investigate, confirm and document the manufacturing capability and capacity of the proposed products in the contract review process, in order to ensure capability & capacity of the organization.

7.2.3 *Customer Communication*

ISO 9001 : 2008, Quality Management systems — Requirements

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

7.2.3.1 *Customer communication — supplemental*

The organization shall have the ability to communicate necessary information, including data, in a customer specified language and format (for example computer aided design data, electronic data exchange).

Wherever possible, organization should identify person(s) for all communication with customer to retain customer focus and fast and relevant communication.

7.3 Design and Development

7.3.1 *Design and Development Planning*

ISO 9001 : 2008, Quality Management systems — Requirements

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

NOTE — The requirements of **7.3** include product and manufacturing process design and development, and focus on error prevention rather than detection.

7.3.1.1 *Multidisciplinary approach*

The organization shall use a multidisciplinary approach to prepare for product realization, including,

a) development/finalization and monitoring of special characteristics;
b) review of FMEA results, if available from power utilities, including actions to reduce potential risks, root cause analysis; and
c) development and review of control plans.

NOTE — A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality production, field engineering and other appropriate personnel.

7.3.2 *Design and Development Inputs*

ISO 9001 : 2008, Quality Management systems — Requirements

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.2.1 *Product design input*

The organization shall identify, document and review the product design inputs requirements, including the following:

a) Customer requirements (contract review) such as special characteristics (*see* **7.3.2.3**), identification and traceability;
b) Use of information: the organization shall have a process to deploy information gained from previous design projects, supplier operational feedback, internal input, plant systems operational feedback site data and other relevant sources, for current and future projects of a similar nature; and
c) Targets for product quality, life, reliability, maintainability, timing and cost.

7.3.2.2 *Product/service offering process design input*

The organization shall identify, document and review the product / service offering process design input requirements, including,

a) product design output data;
b) targets for productivity, process capability;
c) customers requirements, if any; and
d) past experience.

7.3.2.3 *Special characteristics*

The organization shall identify special characteristics [*see* **7.3.3** (d)] and,

a) include all special characteristics in the quality control plan;
b) comply with customer-specified definitions; and
c) identify all process control documents related to the products.

7.3.3 *Design and Development Outputs*

ISO 9001 : 2008, Quality Management systems — Requirements

7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

NOTE Information for production and service provision can include details for the preservation of product.

7.3.3.1 *Product design outputs — supplemental*

The product design output shall be expressed in terms that can be verified and validated to the extent possible against product design input requirements. The product design output shall include,

a) design reliability results;
b) product special characteristics and specifications;
c) product definition including drawings or mathematically based data;
d) product design reviews results, and its implementation;
e) design FMEA; and
f) test methods.

7.3.3.2 *Manufacturing process design output*

The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include but not limited to the following:

a) Specifications and drawings;
b) Manufacturing process flow chart;
c) Manufacturing process FMEAS;
d) Control plan (*see* **7.5.1.1**);
e) Work instructions;
f) Process approval acceptance criteria;
g) Data for quality, reliability, maintainability and measurability; and
h) Methods of rapid detection and feedback of product/manufacturing erection process non-conformities.

7.3.4 *Design and Development Review*

ISO 9001 : 2008, Quality Management systems — Requirements

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

NOTE — These reviews are normally coordinated with the design phases and include manufacturing process design and development.

7.3.4.1 *Monitoring*

Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review.

7.3.5 *Design and Development Verification*

ISO 9001:2008, Quality Management systems — Requirements

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 *Design and Development Validation*

NOTES

1 The validation process normally includes an analysis of field reports for similar products.

2 The requirements of **7.3.5** and **7.3.6** shall apply to both product and manufacturing processes.

ISO 9001 : 2008, Quality Management systems — Requirements

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.6.1 *Design and development validation — supplemental*

Design and development validation shall be performed in accordance with customer requirements including programme timing.

7.3.6.2 *Prototype programme*

When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, wherever possible, the same suppliers, tooling and manufacturing processes as will be used in production.

All performance-testing activities shall be monitored for timely completion and conformity to requirements.

While services and components may be outsourced, the organization shall be responsible for the outsourced services, including technical leadership. For critical services and components supervision and monitoring of the organization shall be taken for the customer.

7.3.6.3 *Product approval process*

The product shall confirm to manufacturing process and procedure approved by the customer, wherever required.

This product and manufacturing process approval procedure shall also be applied to suppliers.

7.3.7 *Control of Design and Development Changes*

ISO 9001 : 2008, Quality Management systems — Requirements

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

ISO 9001 : 2008, Quality Management systems — Requirements

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.1 *Purchasing Process*

7.4.1.1 The organization shall ensure that all requirements given in IS 12040 are fully complied with.

NOTES

1 Purchased products above include all products and services that affect customer requirements such as sub-assembly, part processing, sub-contracting, calibration services, etc. The controls on these products have to put in place to ensure the product quality is maintained to standards as if the work was done in house.

2 When there are mergers, demergers or, acquisitions associated with suppliers or change in manufacturing location, the organization should verify the continuity of the supplier's quality management system and its effectiveness and adequately inform the customer.

3 Any outsourcing or subletting of the contract by supplier should be with the approval of the customer.

7.4.1.2 *Legal conformity*

All purchased products or materials used in product shall conform to applicable statutory and regulatory requirements.

7.4.1.3 *Supplier quality management system development*

The organization shall ensure supplier quality management system development with the goal of supplier conformity with this standard. Conformity with ISO 9001 is the desirable first step in achieving this goal.

7.4.1.4 *Customer-approved sources*

Wherever specified by the contract (for example letter of award, specification), the organization shall purchase products, materials or services from sources approved by the customer.

7.4.2 *Purchasing Information*

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **7.4.2 Purchasing information**
>
> Purchasing information shall describe the product to be purchased, including, where appropriate,
>
> a) requirements for approval of product, procedures, processes and equipment,
> b) requirements for qualification of personnel, and
> c) quality management system requirements.
>
> The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 *Verification of Purchased Product*

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **7.4.3 Verification of purchased product**
>
> The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.4.3.1 *Incoming product quality*

The organization shall have a process to assure the quality of purchased product (*see* 7.4.3) utilizing one or more of the following methods:

a) Receiving inspection and/or testing based on performance (feed back from end users);
b) Quality surveillance of supplier sites; and
c) Equipment or component evaluation by a designated independent laboratory.

7.4.3.2 *Supplier monitoring*

Supplier performance shall be monitored through the following indicators:

a) Delivered product quality;
b) Customer schedule disruptions including field feedback;
c) Delivery schedule performance; and
d) Supplier rating system (*see* IS 12040).

The organization shall promote supplier monitoring of the performance of their manufacturing processes.

7.5 Production and Service Provision

7.5.1 *Control of Production and Service Provision*

ISO 9001 : 2008, Quality Management systems — Requirements

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment,
d) the availability and use of monitoring and measuring equipment,
e) the implementation of monitoring and measurement, and
f) the implementation of product release, delivery and post-delivery activities.

7.5.1.1 *Quality control plan*

The organization shall,

a) develop quality control plans at the system, sub-system, component and/or material level for the product supplied, including those for processes involved; and
b) ensure customer approval for major equipments/items as agreed in the contract.

The quality control plan shall,

1) list the controls used for the manufacturing process control;
2) include methods for monitoring of control exercised over special characteristics (*see* **7.3.2.3**) defined by both the customer and the organization;
3) include the customer-required information, if any, and
4) Quality control plans shall be reviewed and updated when any change occurs affecting product, manufacturing process supply sources.

NOTE — Customer approval is required after review or update of the quality control plan.

7.5.1.2 *Work instruction*

The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. These instructions shall be accessible for use at the place of work.

These instructions shall be derived from, the quality control plan and the product realization process.

7.5.1.3 *Preventive and predictive maintenance*

The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.

7.5.1.4 *Management of production tooling for outsourcing*

The organization shall implement a system to monitor resources for tool and gauge design, fabrication and verification activities. If any work is outsourced.

7.5.2 *Validation of Processes for Production and Service Provision*

ISO 9001 : 2008, Quality Management systems — Requirements

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable,

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (see 4.2.4), and
e) revalidation.

7.5.2.1 *Validation of processes for production and service provision — supplemental*

The requirements of **7.5.2** shall apply to all processes where the resulting output cannot be verified by subsequent monitoring or measurement for production and service provision.

7.5.3 *Identification and Traceability*

ISO 9001 : 2008, Quality Management systems — Requirements

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.3.1 *Identification and traceability*

System shall be laid down for traceability of items both from safety and statutory and maintenance/ replacement or life extension point of view..

7.5.4 *Customer Property*

ISO 9001 : 2008, Quality Management systems — Requirements

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization’s control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

7.5.5 *Preservation of Product*

ISO 9001 : 2008, Quality Management systems — Requirements

7.5.5 Preservation of product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.5.5.1 *Storage and inventory*

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals.

The organization shall use an inventory management system to optimize inventory turns over time and ensure stock rotation, by as 'first-in-first-out (FIFO)' just in time method. Obsolete product shall be controlled in a similar manner to non-conforming product.

7.6 Control of Monitoring and Measuring Devices

ISO 9001 : 2008, Quality Management systems — Requirements

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are .carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
b) be adjusted or re-adjusted as necessary;
c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

7.6.1 *Calibration/Verification Records*

Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee and customer-owned equipment, shall include,

a) equipment identification, including the measurement standard against which the equipment is calibrated;

b) calibration cycle (*see* IS/ISO/IEC 17025).

7.6.2 *Laboratory Requirements*

An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test or calibration services. This laboratory shall specify and implement, as a minimum, technical requirements for,

a) adequacy of the laboratory procedures,
b) competency of the laboratory personnel,
c) testing of the product,
d) capability to perform these services correctly, traceability to the relevant process standard, and
e) review of the related records.

NOTE — Accreditation to IS/ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory conformity to this requirement but is preferred.

8 Measurement, Analysis And Improvement

8.1 General

ISO 9001 : 2008, Quality Management systems — Requirements

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to product requirements,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 *Customer Satisfaction*

NOTE — Consideration should be given to both internal and external customers.

ISO 9001 : 2008, Quality Management systems — Requirements

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

8.2.1.1 *Customer satisfaction — supplemental*

Customer satisfaction with the organization shall be monitored through continual evaluation of performance of the realization processes. Performance indicators shall be based on objective data and include,

a) delivered equipments performance;

b) customer feed back including site failures;
c) delivery schedule performance; and
d) customer satisfaction related to quality or delivery issues.

The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.

8.2.2 *Internal Audit*

ISO 9001 : 2008, Quality Management systems — Requirements

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see 4.2.4).

The management, responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

8.2.2.1 *Quality management system audit*

The organization shall audit its quality management system to verify compliance with this standard. Access shall be provided for quality management system audits surveillance to customers.

8.2.2.2 *Manufacturing process audit*

The organization shall audit each manufacturing process to determine its effectiveness.

8.2.3 *Monitoring and Measurement of Processes*

ISO 9001 : 2008, Quality Management systems — Requirements

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.3.1 *Monitoring and measurement of manufacturing processes*

The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control. The results of process studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria.

The organization shall initiate a control plan for characteristics that are unstable. These plans shall include segregation of product after 100 percent inspection as appropriate. A corrective and preventive action plan shall be completed by the organization, indicating specific timing and assigned responsibilities to ensure that the process becomes stable and capable. These plans shall be periodically reviewed with and approved by the customer, whenever so required.

8.2.4 *Monitoring and Measurement of Product*

ISO 9001 : 2008, Quality Management systems — Requirements

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of Non-conforming Product

ISO 9001 : 2008, Quality Management systems — Requirements

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application;
d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

8.3.1 *Control of Non-conforming Product — Supplemental*

Equipment with unidentified or suspect status shall be classified as non-conforming product (*see* **7.5.3**).

8.3.2 *Customer Information*

Customers shall be informed promptly in the event that non-conforming equipment has been manufactured along with proposed corrective and preventive actions.

8.4 Analysis of Data

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **8.4 Analysis of data**
>
> The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.
>
> The analysis of data shall provide information relating to
>
> a) customer satisfaction (see 8.2.1),
> b) conformity to product requirements (see 8.2.4),
> c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
> d) suppliers (see 7.4).

8.4.1 *Analysis and Use of Data*

Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support the following:

a) Development of priorities for prompt solutions to customer-related problems; and
b) Determination of key customer-related trends and correlation for status review, decision- making and long term planning.

NOTE — Data should be benchmarked with those of competitors.

8.5 Improvements

8.5.1 *Continual Improvement*

> **ISO 9001 : 2008, Quality Management systems — Requirements**
>
> **8.5 Improvement**
>
> **8.5.1** *Continual Improvement*
>
> The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.1.1 *Continual improvement of the organization*

The organization shall define a process for continual improvement. See examples in Annex B.

8.5.1.2 *Manufacturing process improvement*

Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters.

8.5.2 *Corrective Action*

ISO 9001 : 2008, Quality Management systems — Requirements

8.5.2 Corrective Action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken (see 4.2.4), and
f) reviewing the effectiveness of the corrective action taken.

8.5.2.1 Special emphasis shall be accorded to root cause analysis to major quality non- conformances on products like turbine generator and boiler components, where it is not possible to replace items with long delivery cycles and it is imperative to avoid any reoccurrence.

8.5.3 *Preventive Action*

ISO 9001 : 2008, Quality Management systems — Requirements

8.5.3 Preventive Action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken (see 4.2.4), and
e) reviewing the effectiveness of the preventive action taken.

8.5.3.1 In view of a complex process orientation of power equipments it is important that prevention of non-conformities is the key focus area in the systems implementation.

ANNEX A

(*Clause* 3.1.1)

QUALITY PRACTICES AND PROCEDURES RELATED TO QUALITY CONTROL PLAN

A-1 Quality Control Plan

A-1.1 Manufacturing Quality Control Plan

The manufacturing quality plan covers all the activities including type tests, raw material controls, in process controls and final inspection including acceptance tests and checks on packing and preservation.

A-1.2 Field Quality Control Plan

The field quality plan covers all activities from receipt of material or equipment, incoming inspection and storage, pre-erection, pre-assembly, erection or installation, alignment or testing and commissioning.

A-1.3 Maintenance Quality Control Plan

The maintenance quality plan includes all activities and controls during opening of equipment, repair/replacement, testing/inspection, assembly checks and commissioning checks.

A-2 Elements Covered In The Quality Control Plan

a) Raw material controls;
b) In process controls;
c) Final inspection controls;
d) Vendor approval/approved vendor;
e) Type/prototype test or certification requirements;
f) Record requirements;
g) History documents;
h) Characteristics to be checked with corresponding tests;
j) Criticality of the checks;
k) Quantum of check and procedure and acceptance/rejection criteria;
m) Painting and packing details;
n) Storage and preservation instructions;
o) Welding and NDT requirements;
p) Personnel qualification requirements for special processes;
q) Performance test requirements; and
r) Witnessing requirements of agencies involved.

ANNEX B

(*Clause* 8.5.1.1)

PROCESS FOR CONTINUAL IMPROVEMENT

B-1 A strategic objective of an organization should be the continual improvement of processes in order to enhance the organization's performance and benefit its interested parties.

There are two fundamental ways to conduct continual process improvement, as follows:

a) Breakthrough projects which either lead to revision and improvement of existing processes or the implementation of new processes; these are usually carried out by cross-functional teams outside routine operations;

b) Small-step ongoing improvement activities conducted within existing processes by people. Breakthrough projects usually involve significant redesign of existing processes and should include,

  1) definition of the objectives and an outline of the improvement project;
  2) analysis of the existing process (the 'as-is' process) and realizing opportunities for change;
  3) definition and planning of improvement to the process;
  4) implementation of the improvement;
  5) verification and validation of the process improvement; and
  6) evaluation of the improvement achieved, including lessons learned.

Breakthrough projects should be conducted in an effective and efficient way using project management methods. After completion of the change, a new project plan should be the basis for continuing process management.

People in the organization are the best source of ideas for small-step or ongoing process improvement and often participate as work groups. Small-step ongoing process improvement activities should be controlled in order to understand their effect. The people in the organization that are involved should be provided with the authority, technical support and necessary resources for the changes associated with the improvement.

Continual improvement by either of the methods identified should involve the following:

i) *Reason for improvement* — A process problem should be identified and an area for improvement selected, noting the reason for working on it.

ii) *Current situation* — The effectiveness and efficiency of the existing process should be evaluated. Data to discover what types of problems occur most often should be collected and analysed. A specific problem should be selected and an objective for improvement should be set.

iii) *Analysis* — The root causes of the problem should be identified and verified.

iv) *Identification of possible solutions* — Alternative solutions should be explored. The best solution should be selected and implemented; that is the one that will eliminate the root causes of the problem and prevent the problem from recurring.

v) *Evaluation of effects* — It shoulde then be confirmed that the problem and its root causes have been eliminated or their effects decreased, that the solution has worked, and the objective for improvement has been met.

vi) *Implementation and standardization of the new solution* — The old process should be replaced with the improved process, thereby preventing the problem and its root causes from recurring.

vii) *Evaluation of the effectiveness and efficiency of the process with the improvement action completed* — The effectiveness and efficiency of the improvement project should be evaluated and consideration should be given for using its solution elsewhere in the organization.

The process for improvement should be repeated on remaining problems, developing objectives and solutions for further process improvement.

ANNEX C

(*Foreword*)

COMMITTEE COMPOSITION

Composition of Quality Management Sectional Committee, MSD 2

Organization	*Representative(s)*
Directorate General of Quality Assurance, New Delhi	Shri R. Nandakumar (***Chairman***)
Association of Certification Bodies in India, Mumbai	Shri Ravindra Kumar Shri A. Venkataram (*Alternate*)
Bajaj Auto Limited, Pune	Shri C. D. Bhosale Shri P. P. Patwardhan (*Alternate*)
Bharat Heavy Electricals Ltd, Hyderabad	Shri D. Vijayababu Shri K. Sudarsana Rao (*Alternate*)
Confederation of Indian Industry, New Delhi	Shri Anupam Kaul Shri P. Girish (*Alternate*)
Department of Industrial Policy & Promotion, Ministry of Industry, New Delhi	Representative
Development Commissioner, Micro Small and Medium Enterprises (DCMSME), New Delhi	Shri B. S. Srivastava
Directorate General of Quality Assurance, New Delh	Shri R. A. Govardhan
Directorate General of Supplies & Disposals, New Delhi	Shri S. C. Mondal
Directorate of Health Services, Delhi	Dr. Vijoy Kumar
Directorate of Standardization, New Delhi	Gp Capt S. K. Mittal Col Sanjay Bajpai (*Alternate*)
Engineers India Ltd, New Delhi	Shri Adil Firoze Shri Mukesh Meena (*Alternate*)
Export Inspection Council of India, New Delhi	Dr S. K. Saxena Shri Rajiv Raizada (*Alternate*)
Federation of Indian Chambers of Commerce and Industry, New Delhi	Shri S. C. Arora Shri Mritunjay Kumar (*Alternate*)
Glaxosmithkline Consumer Healthcare Ltd, Sonepat	Shri Balachandra Nadig Shri Anil M. Chaudhari (*Alternate*)
Indian Association for Productivity, Quality & Reliability, Kolkata	Shri Arun Malik Brig D. K. Joshi (*Alternate*)
Indian Council of Agricultural Research, New Delhi,	Dr S. Mauria Dr S. Ganesan (*Alternate*)
Indian Institute of Technology, New Delhi	Representative
Indian Statistical Institute, Kolkata	Representative
International Management Institute, New Delhi	Representative
Karnataka State Road Transport Corporation, Bangalore	Shri C. G. Anand Shri Mallikarjun (*Alternate*)
Larsen & Toubro Limited, Mumbai	Shri N. Sathyan Shri N. V. Wagle (*Alternate*)
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ALSTOM Projects India Limited, Noida	Shri Ravi Kapoor
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